

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the article was represented as a drug suitable for intravenous use and it was not suitable for such use in that it was contaminated with viable micro-organisms and pyrogens.

DISPOSITION: February 12, 1954. Default decree of condemnation and destruction.

4372. Adulteration and misbranding of liver-folic acid-B₁₂ and Foliver. U. S. v. 30 Vials, etc. (F. D. C. No. 36397. Sample Nos. 58616-L, 58617-L.)

LABEL FILED: February 18, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about October 2 and 7, 1953, from Philadelphia, Pa.

PRODUCT: 30 vials of *liver-folic acid-B₁₂* and 41 vials of *Foliver* at Detroit, Mich. Analyses showed that the products contained less than 50 percent of the declared amount of vitamin B₁₂.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess, namely, 60 micrograms of vitamin B₁₂ per cubic centimeter.

Misbranding, Section 502 (a), the statement "Each cc. contains: Vit. B₁₂ * * * 60 Mcg." appearing on the labels of the articles was false and misleading as applied to the articles, which contained less than 60 micrograms of vitamin B₁₂ per cubic centimeter.

The articles were adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 16, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4373. Misbranding of C-Tone. U. S. v. 87 Bottles, etc. (F. D. C. No. 36158. Sample No. 26489-L.)

LABEL FILED: December 3, 1953, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 22 and 30 and November 4, 1953, by *Balanced Foods, Inc.*, from New York, N. Y.

PRODUCT: 87 8-ounce bottles of *C-Tone* at Philadelphia, Pa., together with a number of circulars entitled "Which of These Dread Killers Threaten Your Advancing Years?"

LABEL, IN PART: (Bottle) "Rich In Activated Enzymes *C-Tone* The Natural Vitamin C Tonic A splendid aid in quickly correcting conditions caused by deficiency of Vitamin C in the diet. This natural concentrate also supplies other essential nutritional factors as well as generous amounts of Pectin. Four tablespoons furnish: Natural Vitamin C 250 mg. Natural Rutin (Vitamin P Complex) 5 mg. Natural Vitamin K 1 mg. Natural Niacin 0.08 mg. Natural Pectin (Protopectins incl.) 500 mg. Natural Citric Acid 57 mg. Natural Chlorophyll 0.01 mg. and small amounts of natural Vitamin B₁ and B₂. Calcium and Phosphorus in a vegetable extract base rich in activated enzymes. * * * Sale and Exclusive Distributors *Byrne Products, Inc.* New York 7, N. Y."

*See also Nos. 4369, 4372.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Rich In Activated Enzymes" and "Vitamin C Tonic" were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of enzyme content and was effective as a tonic, whereas the article was of no value because of its enzyme content and was not a tonic.

Further misbranding, Section 502 (a), certain statements in the above-mentioned circulars accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells, and that the article was effective to provide energy and improve digestion. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: February 10, 1954. Default decree of condemnation and destruction.

4374. Misbranding of ACC capsules. U. S. v. 8 Cases, etc. (F. D. C. No. 36108. Sample No. 58598-L.)

LIBEL FILED: November 13, 1953, Northern District of Indiana.

ALLEGED SHIPMENT. On or about September 1 and October 5, 1953, from Baudette, Minn.

PRODUCT: 8 cases, each containing 100 bottles, of *ACC capsules* at Portland, Ind., in the possession of Alfalfa Concentrate, Inc., together with a number of leaflets designated "Announcing! ACC Alfalfa Capsules."

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed locally for the consignee and were distributed to wholesale drug firms along with the product for use by the drug firms' salesmen.

LABEL, IN PART: (Bottle) "One Hundred Capsules ACC Each Capsule Contains Active Ingredients: Salicylamide..... 3 grs. Inert Ingredients: Extract of Alfalfa..... 5 grs. Suggested Use As an aid in the relief of muscular aches and pains."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for the terrible pains of arthritis and rheumatism and that the alfalfa ingredient was active and contributed to the effectiveness of the article in such conditions. The article was not an adequate and effective treatment for the pains of arthritis and rheumatism, and the alfalfa ingredient was not active and did not contribute to the effectiveness of the article in such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 16, 1954. Default decree of condemnation and destruction.

4375. Misbranding of organic mineral salt. U. S. v. 6 Cases, etc. (F. D. C. No. 36115. Sample No. 54264-L.)

LIBEL FILED: November 12, 1953, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about August 20, 1953, by Dr. E. H. Bronner & Associates, from Los Angeles, Calif.